

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete If Known	
				Application Number	10/728,665
				Filing Date	December 5, 2003
				First Named Inventor	Satyanarayana MEDICHERLA
				Art Unit	1614
				Examiner Name	A. Marschel
Sheet	1	of	3	Attorney Docket Number	219002032800

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶

*EXAMINER: Initial if information considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
T.P.T. ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓	1.	ADAMS et al., "Pyrimidinylimidazole Inhibitors of CSBP/P38 Kinase Demonstrating Decreased Inhibition of Hepatic Cytochrome P450 Enzymes," Bioorg. Med. Chem. Lett. 8:3111-3116 (1998)	
	2.	BADGER et al., "Pharmacological Profile of SB 203580, a Selective Inhibitor of Cytokine Suppressive Binding Protein/p38 Kinase, in Animal Models of Arthritis, Bone Resorption, Endotoxin Shock and Immune Function," J. Pharmacol. Exp. Ther. 279:1453-1461 (1996)	
	3.	BALASA et al., "Islet-Specific Expression of IL-10 Promotes Diabetes in Nonobese Diabetic Mice Independent of Fas, Perforin, TNF Receptor-1, and TNF Receptor-2 Molecules," J. Immunology 165:2841-2849 (2000)	
	4.	BLAIR, "Regulation of Glucose Transport and Glycogen Synthesis in L6 Muscle Cells During Oxidation Stress," J. Biol. Sci. 17:36293-36299 (1999)	
	5.	BURYSEK et al., "The Serine Protease Plasmin Triggers Expression of MCP-1 and CD40 in Human Primary Monocytes via Activation of p38 MAPK and Janus Kinase (JAK)/STAT Signaling Pathways," J. Biol. Sci. 17:36293-36299 (1999)	
	6.	CASTEELS et al., "Prevention of Autoimmune Destruction of Syngeneic Islet Grafts in Spontaneously Diabetic Nonobese Diabetic Mice by a Combination of a Vitamin D ₃ Analog and Cyclosporine," Transplantation 65:1225-1232 (1998)	
	7.	CHEN et al., "Monocyte Chemoattractant Protein-1 is Expressed in Pancreatic Islets from Prediabetic NOD Mice and in Interleukin-1 β -Exposed Human and Rat Islet Cells," Diabetologia 44:325-332 (2001)	
	8.	COLLIS et al., "RPR203494 a Pyrimidine Analogue of the p38 Inhibitor RPR200765A with an Improved In Vitro Potency," Bioorg. Med. Chem. Lett. 11:693-696 (2001)	
	9.	CRUMP, "The Honeymoon Period in Non-Insulin-Dependent Diabetes Mellitus," J. Family Practice 25:78-82 (1987)	
	10.	DEBUSSCHE et al., "Course of Pancreatic β Cell Destruction in Prediabetic NOD Mice: A Histomorphometric Evaluation," Diabete & Metabolisme (Paris) 20:282-290 (1994)	

Examiner Signature	/Timothy Thomas/	Date Considered	08/30/2007
--------------------	------------------	-----------------	------------

sd-360910

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>			Complete If Known		
			Application Number	10/728,665	
			Filing Date	December 5, 2003	
			First Named Inventor	Satyanarayana MEDICHERLA	
			Art Unit	1614	
			Examiner Name	A. Marschel	
Sheet	2	of	3	Attorney Docket Number	219002032800

/T.P.T.	11.	DE LASZLO et al., "Pyrroles and Other Heterocycles as Inhibitors of p38 Kinase," Bioorg. Med. Chem. Lett. 8:2698 (1998)	
	12.	FIJEN et al., "Suppression of the Clinical and Cytokine Response to Endotoxin by RWJ-67657, a p38 Mitogen-Activated Protein-Kinase Inhibitor, in Healthy Human Volunteers," Clin. Exp. Immunol. 124:16-20 (2001)	
	13.	GALLAGHER et al., "Regulation of Stress-Induced Cytokine Production by Pyridinylimidazoles Inhibition of CSBP Kinase," Bioorg. Med. Chem. 5:49-64 (1997)	
	14.	GOEBELER et al., "The MKK6/p38 Stress Kinase Cascade Is Critical for Tumor Necrosis Factor- α -Induced Expression of Monocyte-Chemoattractant Protein-1 in Endothelial Cells," Blood 93:857-865 (1999)	
	15.	HALE et al., "Differential Expression and Activation of p38 Mitogen-Activated Protein Kinase α , β , γ , and δ in Inflammatory Cell Lineages," J. Immunol. 162:4246-4252 (1999)	
	16.	HANCOCK et al., "Suppression of Insulinitis in Non-Obese Diabetic (NOD) Mice by Oral Insulin Administration Is Associated with Selective Expression of Interleukin-4 and -10, Transforming Growth Factor- β , and Prostaglandin-E," Am. J. Patho. 147:1194-1199 (1995)	
	17.	HEINZE and THON, "Honeymoon Period in Insulin-Dependent Diabetes Mellitus," Pediatrician 12:208-212 (1985)	
	18.	HERLAAR and BROWN, "p38 MAPK Signalling Cascades in Inflammatory Disease," Molec. Med. Today 5:439-447 (1999)	
	19.	HOSKER and TURNER, "Insulin Treatment of Newly-Presenting Ketotic Diabetic Patients into the Honeymoon Period," Lancet 18:633-635 (1982)	
	20.	JACKSON et al., "Pharmacological Effects of SB 220025, a Selective Inhibitor of P38 Mitogen-Activated Protein Kinase, in Angiogenesis and Chronic Inflammatory Disease Models," J. Pharmacol. Exp. Ther. 284:687-692 (1998)	
	21.	KEYMEULEN and SOMERS, "Immunointervention in Type 1 (Insulin-Dependent) Diabetes Mellitus," Acta Clinica Belgica 48:86-95 (1993)	
	22.	KIMBLE et al., "Simultaneous Block of Interleukin-1 and Tumor Necrosis Factor Is Required to Completely Prevent Bone Loss in the Early Postovariectomy Period," Endocrinol., 136:3054-3061 (1995)	
	23.	KUMAR et al., "Novel Homologues of CSBP/p38 MAP Kinase: Activation, Substrate Specificity and Sensitivity to Inhibition by Pyridinyl Imidazoles," Biochem. Biophys. Res. Comm. 235:533-538 (1997)	
	24.	LEE et al., "Inhibition of p38 MAP Kinase as a Therapeutic Strategy," Immunopharmacology 47:185-201 (2000)	
	25.	MAHON et al., "Lessons Learned from Use of Cyclosporine for Insulin-Dependent Diabetes Mellitus," Ann. N.Y. Acad. Sci. 696:351-363 (1993)	
	26.	MAKINO et al., "Breeding of a Non-Obese, Diabetic Strain of Mice," Exp. Animal 29:1-13 (1980)	
	27.	MCLAY et al., "The Discovery of RPR 200765A, p38 MAP Kinase Inhibitor Displaying a Good Oral Anti-Arthritic Efficacy," Bioorg. Med. Chem. 9:537-554 (2001)	
	28.	MIYAZAKI et al., "Predominance of T Lymphocytes in Pancreatic Islets and Spleen of Pre-Diabetic Non-Obese Diabetic (NOD) Mice: A Longitudinal Study," Clin. Exp. Immuno. 60:622-630 (1985)	
↓	29.	MORI et al., "Preventive Effects of Cyclosporin on Diabetes in NOD Mice," Diabetologia 29:244-247 (1986)	
	30.	PALMER and MCCULLOCH, "Perspective in Diabetes, Prediction and Prevention of IDDM-	

Examiner Signature	/Timothy Thomas/	Date Considered	08/30/2007
--------------------	------------------	-----------------	------------

sd-360910

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/728,665
				Filing Date	December 5, 2003
				First Named Inventor	Satyanarayana MEDICHERLA
				Art Unit	1614
				Examiner Name	A. Marschel
Sheet	3	of	3	Attorney Docket Number	219002032800

/T.P.T.		1991," Diabetes 40:943-947 (1990)	
	31.	PAVLOVIC et al., "Activation of Extracellular Signal-Regulated Kinase (ERK) 1/2 Contributes to Cytokine-Induced Apoptosis in Purified Rat Pancreatic β -Cells," Eur. Cytokine Netw. 11:267-274 (2000)	
	32.	POSTE et al., "Lipid Vesicles as Carriers for Introducing Biologically Active Materials into Cells," Meth. Cell Biol. 14:33 (1976)	
	33.	RAPOPORT et al., "Thymic T Cell Anergy in Autoimmune Nonobese Diabetic Mice Is Mediated by Deficient T Cell Receptor Regulation of the Pathway of p21 ^{ras} Activation," J. Exp. Med. 177:1221-1227 (1993)	
	34.	RAVELLI, "Macrophage Activation Syndrome," Curr. Opin. Rheumatol. 14:548-552 (2002)	
	35.	REVESZ et al., "SAR of 4-Hydroxypiperidine and Hydroxyalkyl Substituted Heterocycles as Novel p38 Map Kinase Inhibitors," Bioorg. Med. Chem. Lett., 10:1261-1264 (2000)	
	36.	ROGERS and GIEMBYCZ, "Conquering Airway Inflammation in the 21st Century," Drug Discov. Today 3:532-535 (1998)	
	37.	RYU et al., "Reversal of Established Autoimmune Diabetes by Restoration of Endogenous β Cell Function," J. Clin. Invest. 108:63-72 (2001)	
	38.	SALOMON et al., "B7/CD28 Costimulation Is Essential for the Homeostasis of the CD4 ⁺ CD25 ⁺ Immunoregulatory T Cells that Control Autoimmune Diabetes," Immunity 12:431-437 (2000)	
	39.	SHAPIRO et al., "Combination Therapy with Low Dose Sirolimus and Tacrolimus is Synergistic in Preventing Spontaneous and Recurrent Autoimmune Diabetes in Non-Obese Diabetic Mice," Diabetologia 45:224-230 (2002)	
	40.	SPRINKEL et al., "Glucose Potentiates Interleukin-1 β (IL-1 β)-Induced p38 Mitogen-Activated Protein Kinase Activity in Rat Pancreatic Islets of Langerhans," Eur. Cytokine Netw. 12:331-339 (2001)	
	41.	SUGIHARA et al., "Ultrastructural and Immunoelectron Microscopic Studies on Infiltrating Mononuclear Cells in Lymphocytic Submandibulitis in NOD Mice," Histol. Histopathol. 4:397-404 (1989)	
	42.	TABATABAIE et al., "COX-2 Inhibition Prevents Insulin-Dependent Diabetes in Low-Dose Streptozotocin-Treated Mice," Biochem. Biophys. Res. Comm. 273:699-704 (2000)	
	43.	THOMAS and KAY, "Beta Cell Destruction in the Development of Autoimmune Diabetes in the Non-Obese Diabetic (NOD) Mice," Diabetes/Metabolism Res. Rev. 16:251-261 (2000)	
	44.	WADSWORTH et al., "RWJ 67657, a Potent, Orally Active Inhibitor of p38 Mitogen-Activated Protein Kinase," J. Pharmacol. Expt. Therapeut. 291:680-687 (1999)	
	45.	WANG et al., "Structural Basis of Inhibitor Selectivity in MAP Kinases," Structure 6:1117-1128 (1998)	
	46.	YOSHIDA and KIKUTANI, "Genetic and Immunological Basis of Autoimmune Diabetes in the NOD Mouse," Reviews in Immunogenetics 2:140-146 (2000)	
✓	47.	ZHANG et al., "CD28 Co-Stimulation Restores T Cell Responsiveness in NOD Mice by Overcoming Deficiencies in Rac-1/p38 Mitogen-Activated Protein Kinase Signaling and IL-2 and IL-4 Gene Transcription," International Immunology 13:377-384 (2001)	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	/Timothy Thomas/	Date Considered	08/30/2007
-----------------------	------------------	--------------------	------------

sd-360910